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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,513	12/21/2004	Jeremy Marshall	3003-1159	8360

466 7590 07/12/2007  
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EXAMINER
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SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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07/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/518,513

Applicant(s)

MARSHALL, JEREMY

Examiner

Kathleen Sonnett

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3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/21/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 14 and 17 recite the limitation "the two side edges". There is insufficient antecedent basis for this limitation in the claim.
4. Regarding claims 15-17, the exclusion of a transitional phrase in independent claim 15 makes the scope of the claimed subject matter unclear with respect to what limitations are being positively recited in the claim. The transitional phrases "comprising", "consisting essentially of", and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claims (see MPEP 2111.02-2111.03).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

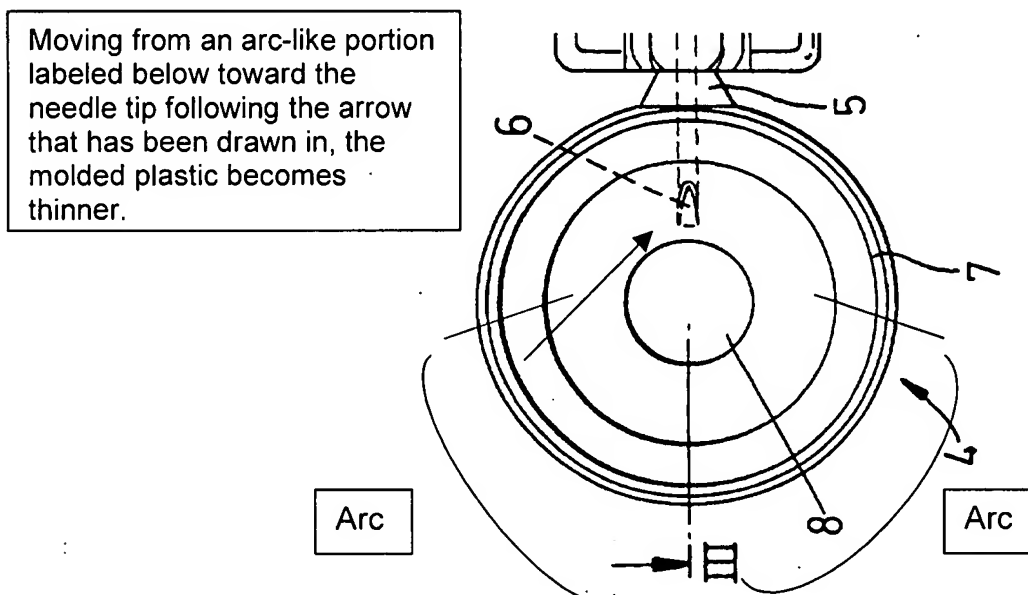
6. **Claims 12-14** are rejected under 35 U.S.C. 102(b) as being anticipated by Crossman (GB 2 352 403). Crossman discloses a lancet having a support body enclosing a needle (6) such that a pointed tip of the needle projects beyond the end of the support body (1) and a

removable guard (4) located over the pointed tip of the needle and interconnected with a support body holding the needle via a breakable neck portion (5) molded with the guard and support body, the guard being formed of a molded plastics material (see abstract). The guard includes an outer edge thickened region leading from the end of the guard remote from the needle tip to a thinner section of the plastic material approaching the needle tip, the plastics material forming a further thickened region about the needle tip but separated from the outer edge region by the thinner section.

7. Looking at fig. 3 of Crossman, the end of the guard remote from the needle tip has a thickened outer edge. Moving straight along the line through which the cross section in fig. 3 is taken (see line III in fig. 1), the thickened region leads to a thinner section of plastic material approaching the tip. The plastics material forms another thickened region about the needle tip, this thickened region separated from the outer edge thickened region by the thinner section.

8. Regarding claim 13, the guard includes a hole (8) that can be considered close to the end of the guard remote from the needle point.

9. Regarding claim 14, the thickened region forms arc-like portions on two side edges of the guard, which lead to the thinner section of plastics material adjacent to the needle tip.



***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 12 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. (U.S. 6,168,606) in view of Higgins (U.S. 3,358,689). Levin discloses a lancet having a support body enclosing a needle (46) such that a pointed tip of the needle projects beyond the end of the support body (41) and a removable guard (80,90) located over the pointed tip of the needle and interconnected with a support body holding the needle via a breakable neck portion (110) joining the guard and support body. The guard includes an outer edge thickened region leading from the end of the guard remote from the needle tip to a thinner section of the plastic material approaching the needle tip, the plastics material forming a further thickened region about the needle tip but separated from the outer edge region by the thinner section (see fig. 5). Levin discloses that the support body and neck are made of plastic but fails to disclose that the guard is made of plastics molded material.

12. However, Higgins discloses that it is old and well known in the art to integrally form a guard and support member with a breakable neck between them using a plastics-molded material because it is an economical manufacturing technique. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Levin to make the guard, support body, and breakable neck region out of plastics molded material so that the three members can be made integrally in an economical manner as made obvious by Higgins.

13. Regarding claim 14, taking two arc-like portions of the distal end (90) of the tab that are along the edge of the tab, these portions lead to a thinner section (any section after 90) of plastics material adjacent the needle tip.

14. **Claims 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman in view of Higgins. Crossman discloses a lancet having a support body enclosing a needle (6) such that a pointed tip of the needle projects beyond the end of the support body (1) and a removable guard (4) located over the pointed tip of the needle and interconnected with a support body holding the needle via a breakable neck portion (5) molded with the guard and support body, the guard being formed of a molded plastics material (see abstract). The guard includes an outer edge thickened region leading from the end of the guard remote from the needle tip to a thinner section of the plastic material approaching the needle tip, the plastics material forming a further thickened region about the needle tip but separated from the outer edge region by the thinner section. Crossman discloses integrally molding the guard and support body (see abstract) but does not disclose the particulars of the mold used to form the device such as the shape or an entry point for the plastic.

15. However, Higgins discloses that it is old and well known in the art to form a lancet using features of the mold to form the shape of the lancet. The needle is held in the mold as seen in fig. 12 and plastics material is injected into the mold via an entry point (88) to crease the guard about the needle tip (col. 4, ll. 46-52). In order to make the lancet of Crossman, it would have been obvious to form the mold with an outer edge thickened hollow region that leads to a thinner hollow section approaching the needle tip and a further enlarged hollow region about the needle tip since such shape a shape would result in the lancet of Crossman as Higgins discloses that injecting plastic into an entry point forms a lancet shaped by the mold.

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16. Regarding claim 16, Crossman discloses that holes (3) are formed by pins that hold the needle during the molding process. Crossman is silent on how hole (8) is formed. However, since Crossman discloses that pins connected to the mold can form holes in the lancet, it would have been obvious to one skilled in the art to form the other hole using a pin. Since the entry point for the plastics is at the distal end of the mold (see fig. 13 of Higgins), and the pin must be located centrally such that it forms hole (8), the material will flow around both sides of the pin.

17. Regarding claim 17, the thickened region forms arc-like portions on two side edges of the guard, which lead to the thinner section of plastics material adjacent to the needle tip (see figure above).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "Glenn K. Dawson".

GLENN K. DAWSON  
PRIMARY EXAMINER

KCS 6/28/2007